December 23, 2021

Meridian Bioscience, Inc.
Heather Planck
Regulatory Affairs Specialist
3471 River Hills Drive
Cincinnati, Ohio 45244

Re: K210976
Trade/Device Name: Curian Campy
Regulation Number: 21 CFR 866.3110
Regulation Name: *Campylobacter fetus* Serological Reagents
Regulatory Class: Class I, reserved
Product Code: LQP
Dated: March 31, 2021
Received: April 1, 2021

Dear Heather Planck:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ribhi Shawar, Ph.D. (ABMM)
Chief
General Bacteriology and Antimicrobial Susceptibility Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

Device Name

Indications for Use *(Describe)*

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

510(k) number: K210976 **Date of Preparation:** December 22, 2021

Owner: **Meridian Bioscience, Inc.**
3471 River Hills Drive
Cincinnati, Ohio 45244 USA
Phone: (513) 271-3700
Fax: (513) 272-5213

Contact: **Primary Contact:**
Heather Planck
Regulatory Affairs Specialist

Trade Name: **Curian® Campy**

Common Name: *Campylobacter Spp.*

Classification Name: *Campylobacter fetus* serological reagents
(21 CFR 866.3110, Product Code LQP)

Predicate Device: *CAMPYLOBACTER QUIK CHEK*
K191456

Device Description

The Curian® Campy assay is a qualitative *in vitro* diagnostic test for the detection of *Campylobacter*-specific antigens in human stool samples collected from individuals with signs and symptoms of gastroenteritis. Curian Campy is intended to detect *C. jejuni*, *C. coli*, *C. upsaliensis*, and *C. lari* in unpreserved or preserved stool in Cary-Blair or C&S transport media. The Curian® Campy assay utilizes fluorescence technology with the cleared Curian® Analyzer (K192817) to detect *Campylobacter*-specific antigens in human stool.

Intended Use / Indications for Use

Curian Campy, for use with the Curian Analyzer, is a rapid, qualitative fluorescent immunoassay for the detection of a *Campylobacter*-specific antigen in human fecal specimens. Curian Campy is intended to detect *C. jejuni*, *C. coli*, *C. upsaliensis*, and *C. lari* in human stool from patients with signs and symptoms of gastroenteritis. The test is intended for use with unpreserved fecal specimens or preserved fecal specimens in transport media. Test results are to be used in conjunction with information available from the patient clinical evaluation and other diagnostic procedures. Curian Campy is intended to aid in the diagnosis of *Campylobacter* infection.

Predicate Device Comparison

Similarities Between the New Device and the Predicate Device		
	NEW DEVICE **Curian™ Campy**	**PREDICATE DEVICE** ***CAMPYLOBACTER QUIK CHEK*** **K191456**
Intended Use/ Indications for Use	Curian Campy, for use with the Curian Analyzer, is a rapid, qualitative fluorescent immunoassay for the detection of a *Campylobacter*-specific antigen in human fecal specimens. Curian Campy is intended to detect *C. jejuni*, *C. coli*, *C. upsaliensis*, and *C. lari* in human stool from patients with signs and symptoms of gastroenteritis. The test is intended for use with unpreserved fecal specimens or preserved fecal specimens in transport media. Test results are to be used in conjunction with information available from the patient clinical evaluation and other diagnostic procedures. Curian Campy is intended to aid in the diagnosis of *Campylobacter* infection.	The *CAMPYLOBACTER QUIK CHEK* test is a rapid membrane enzyme-linked immunosorbent assay for the qualitative detection of a Campylobacter-specific antigen in human fecal specimens. The *CAMPYLOBACTER QUIK CHEK* test is designed to detect C. *jejuni*, C. *coli*, C. *lari*, and C. *upsaliensis* from patients with signs and symptoms of gastroenteritis. The test is intended for use with preserved fecal specimens in transport media and unpreserved fecal specimens. Test results should be considered in conjunction with clinical findings and patient history.
Classification	Class I	Same
Product Code	LQP	Same
Regulation	21 CFR 866.3110	Same
Measured Analyte	*Campylobacte*r-specific antigen	Same
Antibody Format	Monoclonal/Polyclonal	Same
Target Population	Individuals with signs and symptoms of gastroenteritis	Same
Type of Test	Qualitative	Same
Sample Matrix	Human fecal specimen	Same
Specimen Type	Unpreserved fecal specimens and fecal specimens in Cary-Blair and C&S Transport Media	Same
Controls	Positive and negative control included in the kit. Internal Control line	Same
Species Detected	*C. jejuni*, *C. coli*, *C. lari*, and *C. upsaliensis*	Same
Read Result Time	< 30 minutes	Same
Format	Single Use Cassette	Same
Kit Storage	Refrigerated (2-8 ºC)	Same

Differences Between the New Device and the Predicate Device		
	NEW DEVICE **Curian™ Campy**	**PREDICATE DEVICE** ***CAMPYLOBACTER QUIK CHEK*** **K191456**
Technology	Lateral flow fluorescent immunoassay	Rapid membrane ELISA
Interpretation of Results	Results interpretation automated by Curian Analyzer	Visual

NON-CLINICAL PERFORMANCE DATA

Analytical Performance

Precision/Reproducibility

The reproducibility of the Curian Campy assay was determined by testing contrived samples in both stool matrix types (i.e., unpreserved stool and stool preserved in C&S transport media), across three sites (one internal and two external). Samples were created with the *C. jejuni* organism spiked into either preserved or unpreserved pooled negative stool matrix at the following concentrations: high negative (just below C_5), low positive (~C_{95}), moderate positive (3x higher than the C_{95}), and one true negative stool sample. Ten panels of blinded samples with 16 samples per panel were provided to each site per stool matrix type for a total of 320 samples (n=160 unpreserved stool and n=160 preserved stools in C&S media). Testing was conducted at each site twice a day over 5 nonconsecutive days by two operators per day per site and included three different kit lots (2 lots per site). In addition, positive and negative controls were run daily.

The results were consistent among the different locations and exhibited 100% percent agreement (PA) with expected results for the true negative, low positive, and moderate positive preserved stool samples in C&S media. The high negative samples exhibited a PA of 95.3% (95%CI: 90.6% - 97.7%). For unpreserved stool samples, the results were consistent among the different locations and exhibited 100% PA for the true negative and moderate positive samples. The high negative unpreserved stool samples showed a PA of 98.7% (95%CI: 95.2% - 99.6%) and the low positive stool samples showed PA of 82.7% (95%CI: 75.8% - 87.9%), which was lower than expected; under-sampling with the Curian Campy transfer pipette was the cause.

Analytical Sensitivity

Analytical sensitivity studies were performed to determine the analytical limit of detection (LoD) of quantified *Campylobacter* whole cell stocks (*C. jejuni*, *C. coli*, *C. upsaliensis*, and *C. lari*) in human stool matrix for the Curian Campy assay. Three lots of the Curian Campy assay were evaluated. For each kit lot, an LoD was established and confirmed in separate studies for each target *Campylobacter* species across the three sample matrices. The concentrations were calculated in colony forming units per milliliter (CFU/mL) and their equivalent in CFU/test by factoring in the dilutions and the final volume used in the assay. The LoD values determined for the Curian Campy for each species detected by the assay in unpreserved and preserved (C&S and Cary-Blair) stool matrix are listed in the table below.

C. jejuni		***C. coli***		***C. upsaliensis***		***C. lari***	
CFU/mL	CFU/test	CFU/mL	CFU/test	CFU/mL	CFU/test	CFU/mL	CFU/test
Unpreserved Stool Matrix							
$4.00x10^5$	1818	$3.00x10^6$	13636	$1.62x10^6$	7386	$5.00x10^6$	22727
Preserved (C&S) Stool Matrix							
$7.25x10^5$	2266	$1.57x10^7$	49063	$1.18x10^6$	3681	$1.16x10^7$	36250
Preserved (Cary-Blair) Stool Matrix							
$7.25x10^5$	2266	$1.57x10^7$	49063	$2.36x10^6$	7375	$1.16x10^7$	36250

Prozone / Hook Effect

A study was performed to determine the potential for a high dose prozone/hook effect with the Curian Campy assay. Dilutions of quantified *C. jejuni* whole cell stock were prepared in negative sample matrix to create contrived positive samples containing known concentrations of the target antigen. Individual reactions were prepared such that the concentration in each replicate was that of a high positive specimen, approximately 4xLoD - 240xLoD for preserved samples (ranging from $2.70x10^6$ to $1.73x10^8$ CFU/mL) and 7xLoD - 430xLoD for unpreserved samples (ranging from $2.70x\ 10^6$ to $1.73x10^8$ CFU/mL). A total of n=7 dilutions were prepared for both preserved and unpreserved specimen (n=14 total). Each sample dilution was tested in replicates of 5 to determine whether a hook/prozone effect was observed with the Curian Campy assay. A prozone/ hook effect was not observed with the Curian Campy assay when testing samples containing high concentrations of *C. jejuni*.

Cross-Reactivity/Microbial Interference

A cross-reactivity and microbial interference study was performed to determine if microorganisms found in human stool specimens) non-specifically react with the Curian Campy assay, or interfere with detection of *Campylobacter*-specific antigen when present at high concentrations. The specificity of Curian Campy was evaluated by testing bacteria, fungi, and viral strains spiked into unpreserved and preserved stool in C&S media. Each organism was tested with in the absence and presence of *Campylobacter jejuni* (at 2x LoD). Bacteria and fungi were testedat a minimum concentration of $1.0x10^7$ CFU/mL (with the exception of *C. helveticus*) and viruses at minimum concentration of $1.0x10^5$ $TCID_{50}$/mL). For Norovirus,5 preserved clinical stool specimens were evaluated rather than contrived samples.

No cross-reactivity or microbial interference with the Curian Campy assay was observed except for *C. helveticus* (strain ATCC 51209), which was found to be positive at concentrations greater than $3.75x10^6$ CFU/mL in unpreserved stool and $7.50x10^6$ CFU/mL in preserved stool matrix. The organisms evaluated for cross-reactivity are listed below.

Acinetobacter baumannii
Aeromonas hydrophila
Bacillus cereus
Bacillus subtilis
Bacteroides fragilis
Campylobacter concisus
Campylobacter fetus
Campylobacter helveticus
Campylobacter hyointestinalis
Candida albicans
Citrobacter freundii
Clostridium bifermentans
Clostridium difficile
Clostridium perfringens
Edwardsiella tarda
Enterobacter cloacae
Enterococcus faecalis
Escherichia coli
Escherichia coli EIEC
Escherichia coli EPEC
Escherichia coli ETEC
Escherichia coli O157:H7 (non-toxigenic)
Escherichia coli O157:H7 (toxigenic)
Escherichia fergusonii
Escherichia hermanii
Helicobacter pylori
Klebsiella pneumoniae
Lactobacillus acidophilus
Lactococcus lactis
Listeria monocytogenes
Peptostreptococcus anaerobius
Plesiomonas shigelloides
Porphyromonas asaccharolytica
Prevotella melaninogenica
Proteus vulgaris
Pseudomonas aeruginosa
Pseudomonas fluorescens
Salmonella enterica susb. enterica serovar Hilversum
Salmonella enterica susb. enterica serovar Typhimurium
Salmonella enterica susb. enterica serovar Minnesota
Serratia marcescens
Shigella boydii
Shigella dysenteriae
Shigella flexneri
Shigella sonnei
Staphylococcus aureus
Staphylococcus aureus (Cowan's)
Staphylococcus epidermidis
Streptococcus agalactiae
Streptococcus dysgalactiae subsp. equisimilis
Vibrio parahaemolyticus
Yersinia enterocolitica

Adenovirus 1,2, 3, 5, 40, 41
Coxsackievirus B2, B3, B4, B5
Echovirus 9, 11, 18
Enterovirus 68, 69, 70, 71
Human Coronavirus
Human Rotavirus
Norovirus
Parechovirus 1 (formerly Echovirus 22)

Interfering Substances

Interference testing was performed in the presence of chemical and biological substances introduced directly into contrived *C. jejuni* low positive and negative unpreserved and preserved stool samples. Substances and their respective test concentrations evaluated are listed below. Interference was not observed with the Curian Campy assay for any of the substances evaluated at their respective test concentrations.

Barium Sulfate (5% w/v)	Mylanta® (4.2 mg/mL)
Benzalkonium chloride (1% w/v)	Naproxen sodium (5% w/v)
Ciprofloxacin (0.25% w/v)	Nonoxynol-9 (1% w/v)
Ethanol (1% w/v)	Nystatin (1% w/v)
Hog gastric mucin (3.5% w/v)	Palmitic Acid/Fecal Fat (40% w/v)
Human blood (40% v/v)	Pepto-Bismol® (5% v/v)
Human hemoglobin (10.0% w/v)	Phenylephrine (1% w/v)
Human urine (5% v/v)	Polyethylene glycol 3350 (10% w/v)
Hydrocortisone (1% w/v)	Prilosec OTC® (5 µg/mL)
Imodium® A-D (5% v/v)	Sennosides (1% w/v)
Kaopectate® (5% v/v)	Simethicone (10% w/v)
Leukocytes (0.05% v/v)	Stearic Acid/Fecal Fat (40% w/v)
Mesalazine (10% w/v)	Tagamet® (5 µg/mL)
Metronidazole (0.25% w/v)	TUMS® (50 µg/mL)
Mineral Oil (10% w/v)	Vancomycin (0.25% w/v)

Assay Reactivity/ Inclusivity

Several strains of *C. jejuni*, *C. coli*, *C. upsaliensis*, and *C. lari* were used to evaluate the specificity of the Curian Campy assay using both unpreserved and preserved stool (in C&S).

All strains listed below generated positive results when tested.

C. jejuni	***C. coli***	***C. upsaliensis***	***C. lari***
Zeptometrix Z086	ATCC 43482	ATCC BAA-1059	ATCC BAA-1060
ATCC 33292	ATCC 43476	ATCC 49815	ATCC 35222*
ATCC 49350	ATCC 43478	2017/0506H	ATCC 35223*
ATCC 43442	ATCC 43485	2016/1950*	2013/0823H*
ATCC 33560	ATCC BAA-1061	ATCC 43954	2015/0814*
		ATCC 43953*	2015/2983
		2016/2697*	2016/0235*
		2018/0319H*	2015/0519
		2016/1931	2015/1582
		ATCC 700558*	2015/2189

*The following *C. upsaliensis* and *C. lari* strains exhibited elevated LoDs in comparison to the reference strains (ATCC 49816 and ATCC 43675) that were used in the LoD determination:

Species	Strain	Reactivity Level in Unpreserved Stool	Reactivity Level in Stool Preserved in C&S
C. upsaliensis	2016/1950	4x	8x
	ATCC 43953	2x	8x
	2016/2697	56x	78x
	2018/0319H	40x	55x
	ATCC 700558	24x	33x
C. lari	2013/0823H	8x	4x
	2015/0814	8x	4x
	2016/0235	8x	10x
	ATCC 35222	8x	10x
	ATCC 35223	24x	10x

Brush Bridging Study

The Curian Campy assay is for use with unpreserved human stool specimens and human stool specimens preserved in Cary-Blair and C&S transport media. Most specimens are easily sampled using the transfer pipette provided in the kit; however, some unpreserved stool specimens are non-pipettable and require use of a specific brush (i.e., Curian Campy Stool Collection Brush, sold separately by Meridian) to adequately collect the sample for analysis in the Curian Campy assay. Fifty-three non-pipettable stool specimens (5 *Campylobacter* positives and 48 negatives) were processed with the brush during the prospective and archived clinical studies, combined.

To further support use of the brush with the Curian Campy assay, an analytical bridging study was performed that evaluated a panel consisting of contrived positive and negative samples collected/processed with the brush. Contrived positive samples were generated by spiking *C. jejuni* (strain ATCC #BAA-1234) into negative, non-pipettable stool samples. Ten samples were prepared at 3x LoD and 25 samples were prepared at 5x LoD. Twenty-five negative samples were also tested. Three non-expert operators tested each sample at one internal site. All positive samples gave the expected positive results, and all negative samples were negative. These results indicate that non-pipettable stool specimens can be collected with the brush prior to testing with the Curian Campy assay.

CLINICAL PERFORMANCE DATA

Clinical Performance

Prospective Study

The Curian Campy assay was evaluated from July 2020 to December 2020 at five clinical study sites representing geographically distinct regions throughout the United States. There were 1,474 specimens from patients with signs and symptoms of gastroenteritis for whom a diagnostic Campylobacter test had been ordered by a practicing physician, prospectively collected and enrolled into the study. All specimens were tested at the study sites with the Curian Campy assay and either had current standard of care *Campylobacter* culture and speciation performed and results available (reference method) or culture and speciation was performed as part of the study. The vast majority of specimens were pipettable and were processed with the Curian Campy pipette included in the kit. A small subset of specimens were non-pipettable and were processed with the Curian Campy Collection Brush (sold separately by Meridian). Clinical performance (sensitivity and specificity) for prospective specimens against the reference method (culture and speciation) are presented in the following table. There were no observable differences in

performance of the Curian Campy assay with respect to study site, storage condition, kit lot, or patient gender or age. Prospective specimens with discordant results between the Curian Campy assay and the reference method were further evaluated using standard of care (SoC) results obtained with an FDA-cleared commercial nucleic acid amplification test (NAAT); results of discordant testing are footnoted below.

Curian Campy Overall Performance for Prospective Specimens versus Culture and Speciation

		Reference Method: Culture and Speciation					
		Positive	**Negative**	**Total**	**Parameter**	**Estimate**	**95% CI**
Curian Campy Assay	**Positive**	18	28**	46	Sensitivity	85.7%	[65.4% - 95.0%]
	Negative	3*	1425	1428	Specificity	98.1%	[97.2% - 98.7%]
	Total	21	1453	1474			

* The Standard of Care (SoC) testing of two of the three false negative specimens by a high sensitivity, FDA-cleared nucleic acid amplification (NAAT) assay showed that one of the specimens produced a negative Campylobacter result, whereas one of the specimens produced a positive Campylobacter result; the third specimen was not subjected to NAAT testing as part of the SoC.

** Of the 28 false positive specimens, 10 were subjected to SoC testing by a high sensitivity, FDA-cleared NAAT assay. Two of these 10 specimens produced a positive Campylobacter result, whereas eight produced a negative Campylobacter result. Eighteen specimens were not subjected to NAAT testing as part of the SoC.

Archived Study

To further estimate sensitivity and specificity of the Curian Campy assay, 290 archived samples with culture and speciation results were retrospectively tested for *Campylobacter* antigen using the Curian Campy assay at all five study sites. The clinical performance (sensitivity and specificity) for archived samples against the reference method (culture and speciation) are presented in the table below.

Curian Campy Overall Performance for Archived Samples versus Culture and Speciation

		Reference Method: Culture and Speciation					
		Positive	**Negative**	**Total**	**Parameter**	**Estimate**	**95% CI**
Curian Campy Assay	**Positive**	28	5	33	Sensitivity	96.6%	[82.8% - 99.4%]
	Negative	1	256	257	Specificity	98.1%	[95.6% - 99.2%]
	Total	29	261	290			

Contrived Study

Additional testing at each site was conducted with contrived samples at 2xLoD and 8xLoD for *C. coli*, *C. upsaliensis*, and *C. lari* and 3 reagent lots. All 210 specimens tested as expected with n=150 positive Campylobacter spp. specimen and n=60 negative specimen yielding 100% correlation with the anticipated results. Both sample matrices were represented with n=105 unpreserved stool specimens and n=105 stool specimens preserved in C&S transport media. The overall performance of the Curian Campy assay compared to the anticipated results is presented in the table below.

Curian Campy Overall Performance for Contrived Specimens versus Contrived Anticipated Results

		Contrived: Anticipated Result					
		Positive	**Negative**	**Total**	**Parameter**	**Estimate**	**95% CI**
Curian Campy Assay	**Positive**	150	0	150	PPA	100.0%	[97.5% - 100.0%]
	Negative	0	60	60	NPA	100.0%	[94.0% - 100.0%]
	Total	150	60	210			

CONCLUSION

The Curian® Campy assay, as supported by the information submitted in this premarket submission, is substantially equivalent to the predicate device (*CAMPYLOBACTER QUIK CHEK*; K191456).